

## CLAIMS

1. A method for making a custom made foot orthosis (10) for engagement inside a footwear (F) and for conformingly fitting against a bottom surface (P) of a foot of a person for correcting anatomic biomechanical deficiencies of the foot 5 and ensuing body deficiencies of the person, said method comprising the steps of:

a) producing a corrective positive mold (32) of the bottom surface (P) of the foot based on a specialist patient assessment and clinical measurement deficiencies of the foot to correct for the anatomic biomechanical deficiencies of 10 the foot;

b) thermoforming a first strip of moldable synthetic rubber material onto the corrective positive mold (32) to produce a thermoformed flexible top layer (12) sized for conformingly fitting against the bottom surface (P) of the foot;

c) thermoforming a moldable core strip onto the top layer (12) to produce 15 a thermoformed flexible reinforcement core layer (14) sized for having a posterior end (16) in alignment with a mid anterior plantar prominence (K) of a calcaneus bone (C) of the foot, and an anterior end (18) in near alignment with metatarsalphalangeal joints (J) defined between metatarsal bones (M) and phalange bones (T) of the foot;

d) thermoforming a second strip of moldable synthetic rubber material onto 20 the top layer (12) and the core layer (14) to produce a thermoformed flexible bottom layer (20), the core layer (14) being more rigid than the top and bottom layers (12, 20); and

e) grinding the top and bottom layers (12, 20) to further correct for the 25 anatomic biomechanical deficiencies of the foot;

thereby, when the foot orthosis (10) is used by the person, the top and bottom layers (12, 20) cushion walking impacts on a calcaneus spine (S) of the calcaneus bone (C) of the foot, while the core layer (14) transmits the walking impacts to a foot surface extending from the mid anterior plantar prominence (K) 30 of the calcaneus bone (C) of the foot to near the metatarsalphalangeal joints (J).

2. The method for making the custom made foot orthosis (10) according to claim 1, wherein step a) comprises the steps of:

- i) producing a negative mold (34) of the bottom surface (P) of the foot;
- ii) modifying the negative mold (34) to produce a corrected negative mold based on the specialist patient assessment and clinical measurement deficiencies of the foot to correct for the anatomic biomechanical deficiencies of the foot;
- iii) producing a positive mold (36) from the corrected negative mold; and
- iv) modifying the positive mold (36) to produce the corrective positive mold (32) based on the specialist patient assessment and clinical measurement deficiencies of the foot to further relieve or add pressure to the foot.

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3. The method for making the custom made foot orthosis (10) according to claim 1, wherein step a) comprises the steps of:

- i) producing a three dimensional computer representation of the bottom surface (P) of the foot;
- ii) modifying the three dimensional computer representation of the bottom surface (P) of the foot to produce a corrected three dimensional computer representation based on the specialist patient assessment and clinical measurement deficiencies of the foot to correct for the anatomic biomechanical deficiencies of the foot; and
- iii) producing the corrective positive mold (32) from the corrected negative three dimensional computer representation.

4. The method for making the custom made foot orthosis according to claim 1, wherein steps b), c) and d) comprise the steps of:

- i) heating the first strip to produce a first heated strip;
- ii) mounting the first heated strip onto the corrective positive mold (32);
- iii) molding the first heated strip that is mounted onto the corrective positive mold (32) to produce the thermoformed flexible top layer (12);
- iv) applying a glue onto the top layer (12) that is mounted on the corrective positive mold (32);
- v) applying a glue onto a face of the core strip;
- vi) heating the core strip to produce a heated core strip;
- vii) mounting the heated core strip onto the top layer (12);

- viii) applying a glue onto a face of the second strip;
- ix) heating the second strip to produce a second heated strip;
- x) mounting the second heated strip onto the top layer (12) and the heated core strip; and
- 5 xi) molding the heated core strip and second heated strip that are mounted onto the top layer (12) to produce respectively the thermoformed core layer (14) and thermoformed bottom layer (20).

5. The method for making the custom made foot orthosis (10) according to  
10 claim 1, wherein the step iii) of molding includes the step of applying a vacuum to  
the heated strip that is mounted onto the corrective positive mold (32) by means  
of a vacuum device to produce the thermoformed flexible top layer (12), and the  
step xi) includes the step of applying a vacuum to the heated core strip and  
second heated strip that are mounted onto the top layer (12) by means of the  
15 vacuum device to produce respectively the thermoformed core layer (14) and  
thermoformed bottom layer (20).

6. The method for making the custom made foot orthosis (10) according to  
claim 1, wherein the moldable core strip is made of a material selected from the  
20 group including: a plastic and a prepreg.

7. The method for making the custom made foot orthosis according to  
claim 1, wherein the moldable synthetic rubber materials are made from a  
mixture of ethylene, vinyl and acetate

25 8. The method for making the custom made foot orthosis according to  
claim 1, wherein step b) further comprises the step of thermoforming a heel strip  
of moldable synthetic rubber material onto the top layer to produce a  
thermoformed heel cushion layer (21) in alignment with a heel (H) of the foot  
30 extending from the mid anterior plantar prominence (K) of the calcaneus bone  
(C) of the foot to a back of the heel (H).

9. The method for making the custom made foot orthosis according to claim 8, wherein the heel strip of moldable synthetic rubber material is thicker and has a lower density than the first and second strips of synthetic rubber materials.

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10. The method for making the custom made foot orthosis according to claim 1, wherein step b) further comprises the step of thermoforming an additional strip of moldable synthetic rubber material onto the top layer (12) to produce a thermoformed additional layer (22).

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11. The method for making the custom made foot orthosis according to claim 10, wherein step b) further comprises the step of thermoforming a heel strip of moldable synthetic rubber material onto the additional layer (22) to produce a thermoformed heel cushion layer (21) in alignment with a heel (H) of the foot 15 extending from the mid anterior plantar prominence (K) of the calcaneus bone (C) of the foot to a back of the heel (H).

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12. The method for making the custom made foot orthosis according to claim 1, wherein step d) further comprises the step of thermoforming an 20 additional heel strip of moldable synthetic rubber material onto the second strip of moldable material to produce a thermoformed heel angular correction layer (23).

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13. The method for making the custom made foot orthosis according to claim 1, further comprising the steps of gun heating and gluing a corrective strip 25 of synthetic rubber material onto the orthosis for further correcting for the anatomic biomechanical deficiencies of the foot.

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14. A custom made foot orthosis (10) for engagement inside a footwear (F) and for conformingly fitting against a bottom surface (P) of a foot of a person 30 for correcting anatomic biomechanical deficiencies of the foot and ensuing body deficiencies of the person, said foot orthosis (10) comprising:

a thermoformed flexible top layer (12) made of a first moldable synthetic rubber material, the top layer (12) having a shape for conformingly fitting against the bottom surface (P) of the foot;

5 a thermoformed flexible reinforcement core layer (14) made of a moldable core material that is molded onto the top layer (12), the core layer (14) having a posterior end (16) aligned with a mid anterior plantar prominence (K) of a calcaneus bone (C) of the foot, and an anterior end (18) aligned near metatarsalphalangeal joints (J) defined between metatarsal bones (M) and phalange bones (T) of the foot; and

10 a thermoformed flexible bottom layer (20) made of a second moldable synthetic rubber material that is molded onto the top layer (12) and the core layer (14), the core layer (14) being more rigid than the top and bottom layers (12, 20); whereby, when the foot orthosis (10) is used by the person, the top and bottom layers (12, 20) cushion walking impacts on a calcaneus spine (S) of the

15 calcaneus bone (C) of the foot, while the core layer (14) transmits the walking impacts to a foot surface extending from the mid anterior plantar prominence (K) of the calcaneus bone (C) of the foot to near the metatarsalphalangeal joints (J).

15. The custom made foot orthosis (10) according to claim 14, wherein the  
20 moldable core material is made of a plastic or a prepreg.

16. The custom made foot orthosis (10) according to claim 14, wherein the moldable synthetic rubber materials are made from a mixture of ethylene, vinyl and acetate

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17. The custom made foot orthosis (10) according to claim 14, further comprising a thermoformed heel cushion layer (21) made of moldable synthetic rubber material that is molded onto the top layer (12) in alignment with a heel (H) of the foot extending from the mid anterior plantar prominence (K) of the calcaneus bone (C) of the foot to a back of the heel (H), the heel strip of  
30 moldable synthetic rubber material being thicker and having a lower density than the first and second strips of synthetic rubber materials.

18. The custom made foot orthosis (10) according to claim 14, further comprising a thermoformed additional layer (22) made of moldable synthetic rubber material that is molded onto the top layer (12).

5 19. The custom made foot orthosis (10) according to claim 18, further comprising a thermoformed heel cushion layer (21) made of moldable synthetic rubber material that is molded onto the additional layer (22) in alignment with a heel (H) of the foot extending from the mid anterior plantar prominence (K) of the calcaneus bone (C) of the foot to a back of the heel (H).

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20. The custom made foot orthosis (10) according to claim 19, further comprising a thermoformed heel angular correction layer (23) made of moldable synthetic rubber material that is molded on a back of the bottom layer (20).